



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,906	01/09/2002	Greta Arnaut	58764.000036	1498
21967	7590	07/14/2005	EXAMINER	
HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109			KUBELIK, ANNE R	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,906

Applicant(s)

ARNAUT ET AL.

Examiner

Anne R. Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57,58,63-69,71,74,76,77 and 79-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 57,63-69,74,79 and 81 is/are allowed.
- 6) ☒ Claim(s) 58,71,76,77,80,83 and 84 is/are rejected.
- 7) ☒ Claim(s) 82 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1638

DETAILED ACTION

1. Claims 57-58, 63-69, 71, 74-77 and 79-84 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The objection to claim 70 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of applicant's cancellation of the claim.
4. The rejection of claims 64, 66-68, 71-76 and 78 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the inventions withdrawn in light of applicant's cancellation or amendment of the claims.
5. The rejection of claims 57-58, 63-70, 74, 76-77 and 79-82 under 35 U.S.C. 103(a) as being unpatentable over Baum et al (US Patent 6,593,293, filed September 1999) in view of Schnepf et al (Microbiol. Mol. Biol. Rev. 62:775-806) in light of Applicant's pointing out that the cited paragraph in Schnepf discusses CryII, not CryI.
6. The rejection of claims 71 and 76 under 35 U.S.C. 103(a) as being unpatentable over Baum et al (US Patent 6,593,293, filed September 1999) in view of Meulewaeter et al (US 6,294,711, filed June 1997) is withdrawn in light of Applicant's amendment of the claims.
7. The rejection of claim 72 under 35 U.S.C. 103(a) as being unpatentable over Baum et al in view of Meulewaeter et al as applied to claim 71 above, and further in view of Corbin et al (US 6,489,542, filed November 1998) is withdrawn in light of Applicant's amendment of the claims.

Art Unit: 1638

8. The rejection of claim 73 under 35 U.S.C. 103(a) as being unpatentable over Baum et al in view of Meulewaeter et al as applied to claim 71 above, and further in view of Mettler et al (US Patent 6,114,608, filed March 1998) is withdrawn in light of Applicant's amendment of the claims.

9. The rejection of claims 75 and 78 under 35 U.S.C. 103(a) as being unpatentable over Baum et al (US Patent 6,593,293, filed September 1999) in view of Malvar et al (US 6,156,573, filed November 1996) is withdrawn in light of applicant's cancellation of the claims.

Claim Objections

10. Claim 71 is objected to because it has an improper article before "leader" in part (b). The objection is repeated for the reasons of record as set forth in the Office action mailed 11 November 2004, as applied to claims 71 and 73. Applicant's arguments filed 10 May 2005 have been fully considered but they are not persuasive.

Applicant urges that in the invention encompasses more than one exact leader sequence and one exact termination and polyadenylation sequence; Applicant further refers to quoted portions of the specification which cite specific references (response pg 9-11).

This is not found persuasive because such genes have only one leader or termination and polyadenylation sequences. It is suggested that applicant submit the cited references if this is not true for the indicated genes.

11. Claim 82 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Transforming a plant with the chimeric gene of claim 63, as

Art Unit: 1638

claimed in claim 69, would inherently protect the plant from the listed insects; thus, claim 82 fails to limit the parent claim.

12. Claim 84 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applying a protein of SEQ ID NO:2 or cell comprising the protein onto a plant, as claimed in claim 83, would inherently protect the plant from all the listed insects, including *Anticarsia gemmatalis*; thus, claim 84 fails to limit the parent claim.

Claim Rejections - 35 USC § 112

13. Claim 77 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 November 2004. Applicant's arguments filed 10 May 2005 have been fully considered but they are not persuasive.

It is unclear in claim 77, line 2, which protein, of the many that can be encoded by any DNA, is the one intended.

Applicant urges that the claim is dependent upon claims 57 and 58, and thus which proteins are covered by the claim are clear (response pg 14).

This is not found persuasive because many proteins can be encoded by any DNA. It is suggested that "said" be replaced with --the truncated insecticidal Cry2Ae--.

Claim Rejections - 35 USC § 102

14. Claims 83-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Baum et al (US Patent 6,593,293, filed September 1999).

Baum et al teach a method comprising apply the protein of SEQ ID NO:2 (claims 9-10; column 50, line 25, to column 55, line 15).

Claim Rejections - 35 USC § 103

15. Claims 58, 77 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baum et al (US Patent 6,593,293, filed September 1999) in view of Audtho et al (1999, Appl. Environ. Microbiol. 65:4601-4605) and further in view of Schnepf et al (Microbiol. Mol. Biol. Rev. 62:775-806).

The claims are drawn to a nucleic acid encoding a protein consisting of amino acids 2-49 to 632 of SEQ ID NO:2 or a protein of SEQ ID NO:2, chimeric genes comprising it, plants transformed with it, and a process for using it to render plants insect resistant.

Baum et al teach a nucleic acid, SEQ ID NO:1, which encodes the instant SEQ ID NO:2. Baum et al also teach the expression of the DNA in plants, including corn and cotton, in chimeric gene constructs behind plant promoters, including the CaMV 35S, the FMV 35S, the wound-inducible mannopine synthase, and the SSU promoters, a 5' leader sequence, and with and without chloroplast, vacuolar or secretion transit peptides, and operably linked to a 3' terminator (column 12, lines 30-43; column 23, lines 1-20; column 57, line 50, to column 63, line 22). The plants would inherently be resistant to *Helicoverpa armigera*, *Anticarsia gemmatilis*, *Sesamia nonagrioides*, *S. inferens*, *Chilo suppressalis*, *C. partellus*, *Scirpophaga incertulas*, *S. innotata*, *Cnaphalocrocis medinalis*, *Marasmia patnalis*, *M. exigua*, and *M. ruralis*. Baum et al do not

Art Unit: 1638

disclose fragments of the nucleic acid encoding a protein consisting of amino acids 2-49 to 632 of SEQ ID NO:2 or of amino acids 1 to 626-631 of SEQ ID NO:2.

Audtho et al teach that another Cry2 protein, Cry2Aa1, is activated by processing at the N-terminal end, with about 49 amino acids being removed from the N-terminus (paragraph spanning the columns, pg 4602, and Table 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the nucleic acids taught by Baum et al, to remove about 49 amino acids from the N-terminus of the protein, as described in Audtho et al. One of ordinary skill in the art would have been motivated to do so because truncation of the modified Cry genes results in more effective expression in plants (Schnepf et al, pg 793, left column, paragraph 3) and to avoid insect resistance (Schnepf et al, pg 795, left column, paragraph 2).

16. Claims 71 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baum et al (US Patent 6,593,293, filed September 1999) in view of Meulewaeter et al (US 6,294,711, filed June 1997).

The claim is drawn to a chimeric gene construct comprising the CaMV 35S promoter, the Petunia chlorophyll a/b leader sequence, a DNA encoding the TpssuAt transit peptide, a DNA encoding SEQ ID NO:2 and the CaMV 3' termination and polyadenylation region.

The teachings of Baum et al are discussed above. Baum et al do not disclose a chimeric gene construct comprising the Petunia chlorophyll a/b leader sequence.

Meulewaeter et al teach a chimeric gene construct comprising the CaMV 35S promoter, the Petunia chlorophyll a/b leader sequence and a DNA encoding a Cry protein (column 39, lines 49-62).

Art Unit: 1638

Corbin et al teach a DNA encoding the TpssuAt transit peptide operably linked in constructs encoding a Cry protein (column 47, lines 11-37).

Mettler et al teach the CaMV 3' termination and polyadenylation region operably linked in constructs encoding a Cry protein (column 8, lines 11-17).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the chimeric gene construct taught by Baum et al, to use the Petunia chlorophyll a/b leader sequence as described in Meulewaeter et al, the TpssuAt transit peptide as described in Corbin et al, and the CaMV 3' termination and polyadenylation region as described in Mettler et al. One of ordinary skill in the art would have been motivated to do so because selection of particular untranslated leader sequence, transit peptide and 3' termination and polyadenylation regions are obvious design choices.

17. Claims 57, 63-69, 74, 79 and 81-82 are free of the prior art, given the failure of the prior art to teach an isolated nucleic acid encoding a protein consisting of amino acids 1 to 626-631 of SEQ ID NO:2.

18. Claims 57, 63-69, 74, 79 and 81 are allowed.

Conclusion

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

The central fax number for official correspondence is (571) 273-8300.

Art Unit: 1638

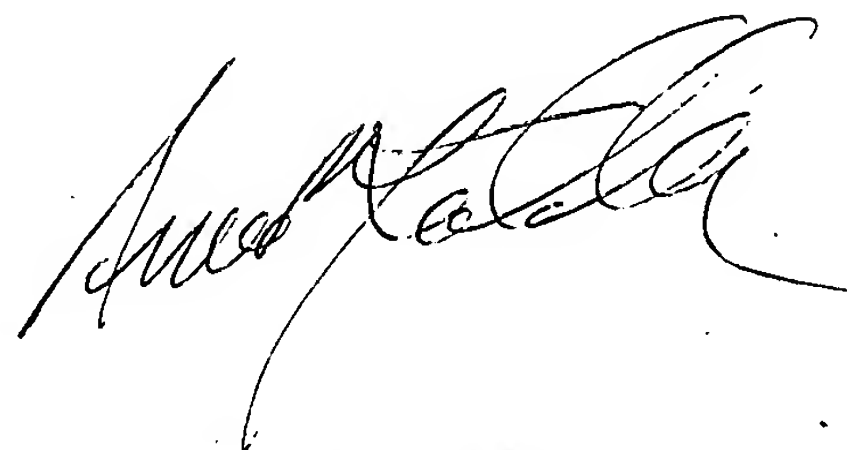
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.

July 8, 2005



ANNE KUBELIK, PH.D.
PRIMARY EXAMINER